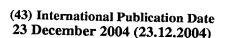
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Declarations under Rule 4.17:

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(54) Title: A NOVEL PROCESS FOR PREPARATION OF VALSARTAN

(57) Abstract: Valsartan of formula (I) is prepared by hydrolysis of valsartan benzyl ester with an alkali metal hydroxide, washing with an organic solvent, acidifying with hydrochloric acid and isolating valsartan from the reaction mixture.

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	ASSIFICATION OF SUBJECT MATTER				
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According B. FIE	g to International Patent Classification (IPC) or to both LDS SEARCHED	national classification and IP	c		
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IPC': C	07D				
Documen	tation searched other than minimum documentation to t	ne extent that such document	s are included i	n the fields searched	
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Electronic	c data base consulted during the international search (na	me of data base and, where p	racticable, sear	ch terms used)	
CAPLU	JS, MedLine, WPI, EPODOC				
C. DO	CUMENTS CONSIDERED TO BE RELEVANT				
		te, of the relevant passages		Relevant to claim No.	
				recevant to claim No.	
×	US 5399578 A (Bühlmayer P, et al.) column 22, lines 53-65.	1-25			
Α	US 5965592 A (Bühlmayer P. et al.) the whole document.	1-25			
A	Jia, Qingzhong, et al., "Synthesis of a valsartan", Zhongguo Yiyao Gongye 2 387, (abstract) CA[online], Chemical a 9 February 2004 (09.02.04)] Retrieve STN-International, Karlsruhe (DE) Acabstract.	1-25			
	CN 1317485 A (Pharmaceutical Co., I Pharmaceutical Factory No. 4) Oct. 13 online [retrieved 9 February 2004 (09 CAPLUS Database, STN-International No. CASPLUS DN 138:89813 abstract.	1-25 ,			
Furth	er documents are listed in the continuation of Box C.	See patent family			
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	actual completion of the international search	Date of mailing of the interr	f mailing of the international search report		
	7 February 2004 (17.02.2004)				
lame and i	mailing adress of the ISA/AT Patent Office	Authorized officer	<u> </u>		
	r Straße 87, A-1200 Vienna	GÖRNER W.			
acsimile N	No. 1/53424/535	Telephone No. 1/53424/558			
orm PCT/	ISA/210 (second sheet) (July 1998)				





International application No. PCT/IN 03/00218-0

	Patent document cited In search report		. Publication date	Patent family member(s)		Publication date	
	A					none	
CN	A	1317485	2001-10-17			none	
US	A	5399578		NO	A	910630	1991-08-20
			•	PH	A	30484	1997-05-2
				HU	В	220073	2001-10-2
				HU	В	219343	2001-10-2
				ΙE	A	910548	1991-08-2
				ZA	A	9101179	1991-11-2
US	A	5965592		NO		03.063.0	
					A	910630	1991-08-20
				PH	A	30484	1997-05-2
				HU	В	220073	2001-10-2
				HU	В	219343	2001-03-2
				IE	A	910548	1991-08-28
				ZA	A	9101179	1991-11-2